



INTERNATIONAL TRADE COMMISSION

Investigation No. 337-TA-833

Certain Digital Models, Digital Data, and Treatment Plans for Use in Making Incremental Dental Appliances, the Appliances Made Therefrom, and Methods of Making Same Notice of Commission Determination to Review the Final Initial Determination of the Administrative Law Judge; Schedule for Filing Written Submissions on Review

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review the final initial determination (“final ID” or “ID”) in the above-captioned investigation.

FOR FURTHER INFORMATION CONTACT: James A. Worth, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3065. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (<http://www.usitc.gov>). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <http://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: This investigation was instituted on April 5, 2012, based upon a complaint filed on behalf of Align Technology, Inc., of San Jose, California (“Align”), on March 1, 2012, as corrected on March 22, 2012. 77 *Fed. Reg.* 20648 (April 5, 2012). The complaint alleged violations of Section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337 (“Section 337”) in the sale for importation, importation, or sale within the United States after importation of certain digital models, digital data, and treatment plans for use in making incremental dental appliances, the appliances made therefrom, and methods of making the same by reason of infringement of certain claims of U.S. Patent No. 6,217,325 (“the ‘325 patent”); U.S. Patent No. 6,471,511 (“the ‘511 patent”); U.S. Patent No. 6,626,666; U.S. Patent No. 6,705,863 (“the ‘863 patent”); U.S. Patent No. 6,722,880 (“the ‘880 patent”); U.S. Patent No. 7,134,874 (“the ‘874 patent”); and U.S. Patent No. 8,070,487 (the ‘487 patent”). The notice of institution named as respondents ClearCorrect Pakistan (Private), Ltd. of Lahore, Pakistan and ClearCorrect Operating, LLC of Houston, Texas (collectively, “the Respondents”).

On May 6, 2013, the administrative law review issued the final ID, finding a violation of Section 337 with respect to the ‘325 patent, the ‘880 patent, the ‘487 patent, the ‘511 patent, ‘863 patent, and the ‘874 patent. The ALJ recommended the issuance of cease and desist orders.

On May 20, 2013, Align, the Respondents, and the Commission investigative attorney each filed a petition for review. On May 28, 2013, each of the parties filed a response thereto. On June 5, 2013, Align filed a statement on the public interest. On June 13, 2013, the Respondents filed a statement on the public interest.

After considering the ID and the relevant portions of the record, the Commission has determined to review the ID in its entirety.

The parties should brief their positions on the issues under review with reference to the applicable law and the evidentiary record. In connection with its review, the Commission is particularly interested in responses to the following questions:

Question 1: Does the language and legislative history of Section 337 provide a basis for interpreting “articles” to cover electronic transmissions? Does the Commission’s remedial cease and desist order in *Certain Hardware Logic Emulation Systems and Components Thereof*, Inv. No. 337-TA-383 (1998), which prohibited the electronic transmission of data, necessarily mean that electronic transmission is importation for purposes of violation within the meaning of Section 337(a)(1)(B)?

Question 2: Is the use of a computer to perform an operation (such as interpolation), which was previously performed in an analog manner, the type of advance which does not render the asserted patent claims nonobvious over the prior art on the facts of this case? Please answer with regard to the factual record in this investigation.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in a respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, *see Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm'n Op. at 9 (December 1994).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the United States Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action.

See Presidential Memorandum of July 21, 2005, 70 *Fed. Reg.* 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding. Complainant and the Commission investigative attorney are also requested to submit proposed remedial orders for the Commission's consideration. Complainant is also requested to state the date that the patents expire and the HTSUS subheadings under which the accused products are imported. The written submissions and proposed remedial orders must be filed no later than close of business on August 8, 2013. Reply submissions must be filed no later than the close of business on August 15, 2013. The written submissions must be no longer than 20 pages and the reply submissions must be no longer than 10 pages. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must do so in accordance with Commission rule 210.4(f), 19 C.F.R. § 210.4(f), which requires electronic filing. The original document and 8

true copies thereof must also be filed on or before the deadlines stated above with the Office of the Secretary. Any person desiring to submit a document to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 C.F.R. § 210.6. Documents for which confidential treatment by the Commission is sought will be treated accordingly. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 C.F.R. Part 210).

By order of the Commission.

Lisa R. Barton

Acting Secretary to the Commission

Issued: July 25, 2013

